NATIONAL MARROW DONOR PROGRAM®

Entrusted to operate the C.W. Bill Young Cell Transplantation Program,
including Be The Match Registry℠

November 05, 2009

Cdr. Elizabeth Montcalm-Smith
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

**Subject:** **Quarterly Performance/Technical Report of the National Marrow Donor Program®**

Reference: Grant Award #N00014-08-1-1207 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Montcalm-Smith:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of July 1, 2009 to September 30, 2009.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention (612-362-3403 or at cabler@nmdp.org).

Sincerely,

Carla Abler-Erickson

Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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1. Contingency Prepardness: Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan.

2. Rapid Identification of Matched Donors : Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event.

3. Immunogenetic Studies: Increase understanding of the immunologic factors important in HSC transplantation.

4. Clinical Research in Transplantation: Create a platform that facilitates multicenter collaboration and data management.

**15. SUBJECT TERMS**
Research in HLA Typing, Hematopoietic Stem Cell Transplantation and Clinical Studies to Improve Outcomes

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NATIONAL MARROW DONOR PROGRAM®

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# Grant Award N00014-08-1-1207

## QUARTERLY
## PERFORMANCE / TECHNICAL REPORT
## FOR
## JULY 01, 2009 to SEPTEMBER 30, 2009
## PERIOD 4

Office of Naval Research

And

The National Marrow Donor Program
3001 Broadway Street N.E.
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# QUARTER PROGRESS REPORT

## Development of Medical Technology for Contingency Response to Marrow Toxic Agents

## July 01, 2009 through September 30, 2009

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| **IIA. Contingency Preparedness – Objective 1:** Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians | |
|---|---|
| **IIA.1.1 Task 1:** Secure Interest of Transplant Physicians | **Period 4 Activity:**<br>• During 2009 a total of 320 RITN center staff successfully completed the Basic Radiation Training (BRT); since its' creation in 2006 1,969 RITN center staff have successfully completed BRT; this is a passing rate of 96.5%. |
| **IIA.1.2 Task 2:** GCSF in Radiation Exposure | **Period 4 Activity:**<br>• No activity this period. |
| **IIA.1 3 Task 3:** Patient Assessment Guidelines and System Enhancements | **Period 4 Activity:**<br>**Contingency:**<br>• Participated in the Donor Contingency Portal projects periodic status meetings and project definition.<br>**STAR Link Web and Do It Yourself (DIY)** application efforts were focused on development of features and enhancements for the Navy Contingency project. This project provides the ability to electronically contact selected donors via email and allow them to complete an online Health History Questionnaire (HHQ) from the DIY platform. Work efforts were focused on the following areas, with a production release date of 10/15/09:<br>• Health History Questionnaire (HHQ) – Enhancements:<br>o Void form enhancement<br>o DIY HHQ Form FDA required Language changes<br>• Online Donor HHQ references added to Search Folder HHQ Summary Screen Setup<br>• Checkbox "Show Detail Status" on Pending Search screen<br>• Initiation of Online HHQ<br>• Review of Online HHQ verification<br>• Report that displays original responses from donor that have completed an Online HHQ |

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| | In the next quarter, pilot testing, metrics capture and analysis will continue with this effort.<br><br>Other efforts for the Contingency Project include:<br><br>• Completed the following project initiation and analysis deliverables to support future releases on the Navy Contingency Project:<br>o Draft Quality Assurance Plan<br>o Draft requirements/use case for iteration 3 (Voids)<br>o Iteration 4 requirements/use case (Accurint)<br>o Define/Tag Affected donor requirements/use case<br>o DIY extension requirements/use case<br>o Communicate to donors requirements/use case<br>o Began documenting requirements for manage affected donor requirements/use case<br><br>• Statistic: DIY Online Donor Registration through www.marrow.org resulted in a **total of** 75,077 between 1/1/08 – 9/30/09.<br><br>**Data Warehouse/Data Mart Reporting:**<br><br>• In the last quarter the Do It Yourself Recruitment (DIY) Data Mart was deployed to production. This Data Mart will provide the foundation for the Navy Contingency reporting of donor contingency response. |
| **IIA 1.4 Task 4:** National Data Collection Model | **Period 4 Activity:**<br><br>• No activity this period. |

| **IIA. Contingency Preparedness – Objective 2:** Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation. | |
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| **IIA.2.1 Task 1:** Contingency Response Network | **Period 4 Activity:**<br>• Supported completion of RITN tasks by participating centers and coordinated the distribution of grant payments to centers once their tasks were satisfactorily completed all tasks.<br>o 90% of RITN centers completed their FY09 tasks; five centers were offered extensions to complete their tasks before the end of calendar year 2009.<br>o Currently there are a total of 57 RITN centers; two were inactive and four new centers joined the network during FY09.<br>• Conducted three Monthly RITN Conference Calls for center contacts to discuss issues related to the completion of tasks at their centers with the intent of sharing best practices between centers.<br>• Created and distributed three "Radiation In the News" radiation event summary reports for distribution to RITN center staff to keep them abreast of radiological related incidents occurring around the globe.<br>• Attended the Oklahoma University Medical Center Tabletop exercise |
| **IIA.2.2 Task 2:** Sibling Typing Standard Operating Procedures | **Period 4 Activity:**<br>• Discussed options with Dr. Confer on how best to accomplish this task with minimal IT systems changes |

| **IIA. Contingency Preparedness – Objective 3:** NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center. | |
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| **IIA.3.1 Task 1:** I.S. Disaster Recovery | **Period 4 Activity:**<br>• Conducted a Business Continuity Exercise with Search & Transplant and Donor Resources departments in September 2009. Key staff was able to access the NMDP production Data Center in Minnetonka from a remote staff recovery site and was able to work through their critical task lists.<br>• Additional hardware was purchased, installed and configured to support Disaster Recovery environment and Business Continuity Exercise. Additional network devices were also set up and configured to support the Disaster Recovery environment and to support Business Continuity tests. |
| **IIA.3.2 Task 2:** Critical Facility and Staff Related Functions | **Period 4 Activity:**<br>• **Business Continuity Planning:**<br>o Completed the development of the organization Business Continuity Plan and acquired Chief Executive Officer approval for final publication and implementation of the plan.<br>o Conducted the organization's first business continuity exercise (BCPeX-2009):<br>▪ 20 staff from Donor Resources and the Search Coordinating Unit conducted critical tasks from a remote non-NMDP location (nearby Ramada hotel).<br>▪ Staff connected to the new Unified Communications system demonstrating that the new Internet based telecommunications system is able to connect staff at any location with the appropriate level of Internet access and necessary equipment.<br>o Completed the first comprehensive review of the critical task and staff list by the Critical Task List Review Committee.<br>o Pandemic influenza preparedness was accomplished:<br>▪ Developed influenza specific HR policies and organizational response plans to be implemented once an NMDP emergency is declared.<br>▪ Informed staff of the developing influenza pandemic situation.<br>▪ Created and conducted training on reducing the spread of influenza in the workplace to 82% of NMDP staff (still ongoing). |

| **IIB. Rapid Identification of Matched Donors – Objective 1:** Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection. | |
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| **IIB.1.1 Task 1:** Increase Registry Diversity | **Period 4 Activity:**<br><br>Five contracted laboratories performed HLA-A, B, DRB1 typing and one laboratory performed HLA-A, B, C, DRB1 typing, on 82,268 newly recruited donors funded by this grant.<br><br>• Blind quality control testing error rate was 0.03%, meeting the project requirement of ≤ 2.0%.<br>• On-time testing completion rate was 98 %, meeting the project requirement of a minimum of 90% of typing results reported within 14 days of shipment of samples.<br><br>**<u>Adult Donor Registry</u>:**<br><br>• To successfully serve all patients in need of cellular transplantation, the Marketing and Communications Department continues to focus on developing and executing strategies and tactics that increase awareness, education and engagement among target audiences. During the July – September 2009 time-frame, we developed marketing materials and tools to support the launch of the "Say it Loud…Save Lives and Be Proud" program. This program is a comprehensive approach to engaging Historically Black College and University (HBCU) students and their community in our mission to save lives. A key component of this program is the launch of a Be The Match[SM] Web site on the HBCU Connect online platform. This platform is the premiere online channel for HBCU students and alumni. The site will serve as a key tool to help educate this community about the need for more African Americans to join the registry and to donate marrow when called. It will also feature stories about HBCU schools that are hosting drive events on campus and stories about committed donors and the lives they have saved.<br><br>Additionally, Marketing and Communications strengthened its outreach to the Hispanic/Latino community by developing key additional educational materials in the Spanish language to enhance this community's drive-related experience and their participation in our mission. |
| **IIB.1.2 Task 2:** Evaluate HLA-DRB1 High Res typing | **Period 4 Activity:**<br><br>• This activity is closed. |

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| **IIB.1.3 Task 3:** Evaluate HLA-C Typing of Donors | **Period 4 Activity:**<br>• This activity is closed. |
| **IIB.1.4 Task 4:** Evaluate Buccal Swabs | **Period 4 Activity:**<br>• Sample Storage Research Study (SSRS) 30 donor samples (frozen blood, blood spotted onto filter paper, and 2 buccal swabs for each donor) were sent to two laboratories for the 2 year time point of the study in September, 2009. Preliminary review of the data shows 100% accuracy in HLA typing, and good quality and quantity of DNA for all samples. 8 samples needed repeat testing at one locus: 2 blood samples, 1 filter paper sample, and 5 buccal swabs. This resulted in a 1.7% repeat rate. All repeat testing was 100% accurate. |
| **IIB 1.5 Task 5:** Enhancing HLA Data for Selected Donors | **Period 4 Activity:**<br>This aim consists of registry-based typing projects, which have the potential to strategically identify and improve the HLA typing and availability of donors most likely to match searching patients from domestic TCs. All strategies being evaluated are extensions of the previous Replacement Donor and Optimal Donor typing projects.<br>• Back-Up Donor Project: While the primary study was completed in December 2007, the NMDP staff has continued to monitor the patient-directed utilization of the 206 donors prospectively typed in this project. To date we have observed the activation of 16 donors for CT requests, followed by 6 workup requests and 3 subsequent stem cell donations. An abstract reporting the results of this study was accepted for a poster presentation at the 2009 ASHI annual meeting.<br>• Optimal Donor Project: While the project was officially completed in 2008, NMDP staff has continued to monitor the patient-directed utilization of the 462 donors prospectively typed in this project. Current follow-up of these donors revealed the activation of 20 donors for CT requests, followed by 2 hold-for-workup requests, 2 workup requests and 1 stem cell donation. An abstract reporting the results of this study was accepted for oral presentation at the 2009 ASHI annual meeting.<br>• Preliminary Search / Donor Contact project (minority donor sub-group): prospective typing of 422 minority donors was completed in late October 2008. Current follow-up of these donors revealed |

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| | the activation of 2 donors for CT requests.<br>• Evaluation of HLA-AB only typed donors potentially matching patients with formal searches: Patient searches with active work-up requests were evaluated and searches identified for which there are relatively few 6/6 matched donors. 691 donors were selected from the HLA-AB only typed pool and tested for HLA-DRB1. Prospective typing was completed in March 2009. Current follow-up of these donors revealed the activation of 7 donors for CT requests on behalf of different patients, 2 workup requests and 1 stem cell donation.<br>• Continuing analysis of patients associated with Optimal Donor project that had zero potential 6/6 donor matches in NMDP hosted registry or BMDW. As previously reported, 4,931 donors were identified who potentially matched the study patients. 1,359 donors with repository samples were selected for prospective typing. AB only donors selected were associated with unique phenotypes not seen in the fully typed donor population or phenotypes with few (2-10) donors. Current follow-up of these donors revealed the activation of 10 donors for CT requests on behalf of 9 different patients, followed by a stem cell donation for a patient who had searched for almost two years. These donors had been on the registry from 8-14.7 years prior to prospective typing, but were then activated for new patients within an average of 228 days. An abstract reporting the results of this study was accepted for poster presentation at the 2009 Annual ASHI meeting.<br>• Performed an additional 460 donor selections for prospective HLA typing using our Optimal Donor selection strategies now for patient phenotype categories with only 1-2 potentially allele-matching donors. Current follow-up of these donors revealed the activation of 5 donors for CT requests on behalf of 5 different patients, within an average of 86 days of the availability of upgrade HLA typing results. |
| **IIB 1.6 Task 6:** Maintain a Quality Control Program | **Period 4 Activity:**<br>• 121 new unique B-LCLs were added to the QC Master inventory. 19 of these cell lines were selected due to rare alleles contained in their haplotypes. Blind QC Swab samples will be created from these cell lines for shipment as needed. |

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| **IIB. Rapid Identification of Matched Donors – Objective 2:** Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments. | |
| **IIB 2.1 Task 1:** Collection of Primary Data | **Period 4 Activity:**<br>• No activity this period. |
| **IIB 2.2 Task 2:** Validation of Logic of Primary Data | **Period 4 Activity:**<br>• This activity is closed. |
| **IIB 2.3 Task 3:** Reinterpretation of Primary Data | **Period 4 Activity:**<br>• This activity is closed. |
| **IIB 2.4 Task 4:** Genotype Lists & Matching Algorithm | **Period 4 Activity:**<br>• Conducted re-interpretation of approximately 270,000 probe results to the HLADB 2.4.0 allele list in production.<br>• Wrote program to "validate and push" probe results making them available to systems using HapLogic. Donors in the registry prior to February, 2007 had already been pushed and have been used for searches; with this quarter's effort primary data from donors stored since 2007 are starting to be used in searches. |
| **IIB. Rapid Identification of Matched Donors – Objective 3:** Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor. | |
| **IIB.3.1 Task 1:** Phase I of EM Haplotype Logic | **Period 4 Activity:**<br>• Approach for HapLogic III presented to the NMDP Histocompatibility Advisory Group on July 9, 2009. Feedback was very helpful to determine scope of work for HapLogic III.<br>• Project Charter and technical documentation created to outline work planned to be done.<br>• Prototype for HapLogic Phase III added ARS logic. Internal validation testing continued in order to test the HapLogic III prototype (which includes x of 10 matching and sorting, x of 8 matching and sorting, and a single value "allele" sort based on a weighted average matching score). |

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| **IIB 3.2 Task 2:** Enhancement of EM Algorithm | **Period 4 Activity:**<br>• Based on genetic distance, the size of the donor cohorts, and data integrity, the 147 detailed race and ethnic categories were combined and pruned to 21 operationally useful categories which will be used for HapLogic III and registry modeling.<br>• High-resolution haplotype frequencies were generated using all DNA-typed donors in the 21 population categories for the A-B-DRB1, C-B, DRB1-DQB1, A-C-B-DRB1, and A-C-B-DRB1-DQB1 loci. |
| **IIB 3.3 Task 3:** Optimal Registry Size Analysis | **Period 4 Activity:**<br>• A preliminary report was issued on September 30th listing the current probabilities of 8/8 and 7/8 match at A,C,B,DRB1 for adult donors and 4/6, 5/6, and 6/6 match at A,B, and DRB1 using criteria for cord blood matching in the 21 population categories. The final report with registry growth scenarios and analysis details will be released next quarter. |
| **IIB 3.4 Task 4:** Target Under-Repre-sented Phenotypes | **Period 4 Activity:**<br>• Feedback was received on prototype using ESRI-ARC GIS Geographical Analysis software regarding better data representation, finding representative frequencies in low population areas, geospatial correlation of 2 variables tools, and how to evaluate data integrity in outliers. In the next quarter planning to update prototype to incorporate that feedback.<br>• Updated agreement for NCOA information sent from ZDI to include latitude/longitude information for use in this project. |
| **IIB 3.5 Task 5:** Bioinformatics Web Site | **Period 4 Activity:**<br>• This activity is closed. |
| **IIB 3.6 Task 6:** Consultants to Improve Algorithm | **Period 4 Activity:**<br>• This activity is closed. |

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| **IIB 3.7 Task 7:** Population Genetics | **Period 4 Activity:**<br>• During the past quarter we worked on building relationships with external collaborators for the development of enhancements to the registry matching models. |
| **IIB 3.8 Task 8:** Haplotype Matching | **Period 4 Activity:**<br>• No activity this period. |
| **IIB 3.9 Task 9:** Global Haplotype/Benchmark | **Period 4 Activity:**<br>• No activity this period. |
| **IIB. Rapid Identification of Matched Donors – Objective 4:** Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care. | |
| **IIB.4.1 Task 1:** Expand Network Communications | **Period 4 Activity:**<br>• No activity this period. |
| **IIB.4.2 Task 2:** Central Contingency Management | **Period 4 Activity:**<br>Donor testing continued for the research project to validate the "actual" 8/8 HLA high resolution match rate for both CAU and AFA patients and supply valuable information regarding donor selection in the event of a contingency. Donors are being tested in rounds of priority for cost efficiency. During this period, three rounds of donor testing were performed (N=1162 loci total) and results compiled for the analysis. Additional testing rounds will continue next quarter to complete the testing required for the analysis. |
| **IIB.4.3 Task 2:** Benchmarking Analysis | **Period 4 Activity:**<br>• This activity is closed. |

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| **IIB.4.4 Task 2:** Expand Capabilities of Collection and Apheresis Centers | **Period 4 Activity:**<br>• This activity is closed |
| **IIC. Immunogenetic Studies – Objective 1:** HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found. | |
| **IIC.1.1 Task 1:** Donor Recipient Pair Project | **Period 7 Activity:**<br>In 1994 a retrospective D/R Pair HLA typing project to characterize class I and class II alleles of donor/recipient paired samples from NMDP's Repository was initiated. The goals of this ongoing research project are to assay the impact of DNA-based HLA matching on unrelated donor transplant outcome, develop strategies for optimal HLA matching, evaluate the impact of matching at alternative HLA loci on transplant outcome and finally to promote the development of DNA-based high resolution HLA typing methodologies.<br>• All outstanding typing issues from prior SGs were compiled and assigned to a Tie-Breaker laboratory. Full analysis and audit will be completed early next quarter.<br>• 273 pairs of sample Group 22 whose period of performance came to a close on April 30, 2009 have been audited and are available for inclusion in research studies.<br>• The project period for SG23 came to a close on August 31, 2009. The contracts for SG23 (400 pairs) testing include intermediate and high resolution HLA. No-Make resolution and discrepancy analyses have been initiated. Audit of the 400 pairs will occur next quarter.<br>• Sample Group 24 (400pairs) was initiated on August 31, 2009. Inclusion of high resolution DPB1 typing on all samples occurred within SG 24. The period of performance is from August 31, 2009 to December 31, 2009.<br>Current HLA matching guidelines for unrelated HCT recommend avoidance of mismatches only within the ARS. This recommendation is based on the hypothesis that amino acid differences outside the ARS are not immunogenic. The ARS allo-reactivity assessment project will give insight into the allowable percent tolerance of matching needed outside of the ARS. |

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| | • Initiated investigation of the first class II non-ARS mismatch (DRB1*140101/1454) where both alleles have been seen in the same genotype. Specific queries of the Be The Match Registry allowed for selection of ninety-nine potential donors to be typed at high resolution.<br>• HLA-A, B, C, DRB1/3/4/5, DQA/B1 and DPB1 typings were completed on all 99 donors. Selection of potential study participants is ongoing. |
| **IIC. Immunogenetic Studies – Objective 2:** Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role. | |
| **IIC 2.1 Task 1:** Analysis of non-HLA loci | **Period 4 Activity:**<br>The Immunobiology Project Results (IPR) database and its applications will allow for storage and analysis of all immunogenetic data collected on NMDP research samples. This database will replace the existing HLA donor/recipient pair's database and facilitate storage and analysis of data from other immunogenetic loci (KIR, microsatellites, single nucleotide polymorphisms, etc).<br>• The Scientific Services and Bioinformatics departments continued to collaborate on the design and development of the IPR database application and tools.<br>• Quality assurance progressed on the application that accepts, validates, and stores incoming HLA and KIR typing data via HML.<br>• Development was initiated for reports that support the business user's ability to track typing requests and their results.<br>• Development was completed for an application which loads transplant center typings.<br>• Development was completed for an application that compares typings between the labs and the transplant centers.<br>• Requirements and specifications were completed for software tools that monitor and resolve typing discrepancies.<br>• Requirements were 100% completed and specifications 80% completed for tools that allow the business user to monitor, alter, and audit data. |

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| | Requirements and specifications were initiated for software that automates the processing flow of the data from loading to data analysis to comparison between the labs to auditing to selection for study. |
| **IIC 2.2 Task 2:** Related Pairs Research Repository | **Period 4 Activity:**<br>• No activity this period. |
| **IIC 2.3 Task 3:** CIBMTR Integration | **Period 4 Activity:**<br>• No activity this period. |
| **IID. Clinical Research in Transplantation – Objective 1:** Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response. | |
| **IID.1.1 Task 1:** Observational Research, Clinical Trials and NIH Transplant Center | **Period 4 Activity:**<br>**AGNIS Activity:**<br>• Completed development and internal quality assurance for AGNIS 2.0 to publish functionality supporting Forms 2400, 2450 and 2900<br>• Provided support for external testing and development using AGNIS 2.0 Publish functionality<br>• Completed development and internal QA for AGNIS 2.0 form Submission for Form 2900, functionality released to external development site for use by transplant centers<br>• Completed development for AGNIS 2.0 form Submission for Forms 2400 and 2450.<br>• Completed development and QA of a Meta Data Tool to assist transplant center data mapping to caDSR curated forms, released with supporting documentation via AGNIS.net website.<br>• Completed requirements for the AGNIS Enhanced Staging Client, this tool will support transplant center submission and retrieval of forms through AGNIS, requirements have been review with transplant centers on the weekly AGNIS conference call<br>• Successfully hosted an IT Summit at NMDP attended by over 110 transplant center data management and IT staff, which included various presentations on AGNIS and data management related topics |

**FormsNet Activity:**

- FormsNet v2.9 (Donor Forms and Functionality). Delivered as planned on August 6, 2009.
- Development and Quality Testing continues for FormsNet v2.10 (26 Recipient Forms updates/modifications). Planned delivery is November 23rd, 2009.
- Development and Quality Testing continues for FormsNet v2.11 (Clinical Trials module and 17 RDSafe Forms). Planned delivery is November 23rd, 2009.
- Analysis has begun for FormsNet v3.0 with major upgrades to Web-interface and underlying web services. Planned delivery is late winter 2010.

**Observational Research**

- Staff continued work on various observational studies within the area of Immunobiology and GVHD and Graft Sources Working Committees.
- A total of 20 abstracts were submitted to the 2009 ASH meetings during this reporting period from all the CIBMTR Working Committees of which one was from a committee supported by this grant.

**Prospective Studies; RCI BMT**

- During this report period, accrual to the BMT CTN PBSC vs. Marrow trial was completed. Follow up activities will continue for two years on the patients and three years on the donors.
- Adult Double Cord trial activity during this period included four patients being enrolled for a total of 21 patients accrued to this study, giving us a 38% completion rate. Staff continues to coordinate and complete monthly PI and coordinator calls, manage data collection and monitor sites. During this report period staff updated a variety of coordinator and site materials.
- Revlemid trial activity continued during this period. Sites have enrolled patients onto this study using the EMMES developed data capture forms. Minor revisions have been identified and have or are currently being revised.

Note: The sentence related to staff time for the 07-Revlimid trial included in the last Quarterly Report for Period 3 and submitted in August 2009 was included in error.

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| **IID.1.2 Task 2:** Research with NMDP Donors | **Period 4 Activity:**<br>• Staff continued support of a Donor Ethnicity study with Dr. Galen Switzer from the University of Pittsburgh.<br>• Staff continued to collaborate on a COG KIR study. Activities include facilitating the collection of a donor blood sample and shipment to the study lab. To date, 24 patients have been enrolled and 83 donor samples requested.<br>• The protocol for long-term donor follow-up, consisting of revised questions, was finalized. The protocol is on track to complete the approval process in fall 2009. Work was begun on identifying and streamlining the operational processes needed to implement this protocol and proceed with centralization of the follow-up.<br>• During this review period staff was involved in optimizing processes to support research studies that include donor samples. |
| **IID.1.3 Task 3:** Expand Immuno-biology Research | **Period 7 Activity:**<br>The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies<br>• The scientific director and Ph.D. statisticians attended and participated in the CIBMTR External Scientific Agenda review.<br>• Five manuscripts were submitted for publication:<br>o David Valcarcel, et al. *One Antigen Mismatched Related vs. HLA-Matched Unrelated Donor Hematopoietic Transplantation in Adults with Acute Leukemia: CIBMTR Results in the Era of Molecular Typing.* Submitted to Blood.<br>o Stephen Spellman, et al. *The Detection of Donor-Directed, HLA-Specific Alloantibodies in Recipients of Unrelated Hematopoietic Cell Transplantation is Predictive of Graft Failure.* Submitted to Blood.<br>o Susana Marino, et al. *Mismatched Unrelated Donor Stem Cell Transplantation: Identification of HLA Class I Amino Acid Substitutions Associated with Survival at Day 100.* Submitted to Blood.<br>o David McDermott, et al. *Donor and Recipient Chemokine Receptor CCR5 Genotype is Associated with Survival after Bone Marrow Transplantation.* Submitted to Blood. |

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| | ○ Yume Nguyen, et al. *Insufficient Evidence for Association of NOD2/CARD15 or Other Inflammatory Bowel Disease-Associated Markers on GVHD Incidence or Other Adverse Outcomes in T-Replete, Unrelated Donor Transplantation*. Submitted to Blood.<br>• Two abstracts were submitted and accepted for presentation at the 2009 American Society of Hematology annual meeting:<br>○ Yasuo Morishima, et al. *Impact of Donor-Recipient Ethnicity on Risk of Acute Graft-Versus-Host Disease, Leukemia Relapse and Survival in Hematopoietic Stem Cell Transplantation from HLA-Compatible Unrelated Donors. A Report from the International Histocompatibility Workshop Group.* Accepted for oral presentation.<br>○ Sarah Cooley, et al. *Choosing Donors with Favorable KIR B Genotypes for Unrelated Hematopoietic Transplantation Results in Superior Relapse Protection and Better Relapse-Free Survival for Patients with AML*. Accepted for oral presentation.<br>Funding for CIBMTR IBWC studies:<br>• Research funds were awarded to support DNA extraction and preparation of 408 samples for a study evaluating genome wide genetic diversity and the impact on acute graft versus host disease. The extractions will be completed early next quarter. |

## ACRONYM LIST

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| AABB | American Association of Blood Banks | ICRHER | International Consortium for Research on Health Effects of Radiation |
| AGNIS | A Growable Network Information System | IS | Information Services |
| AML | Acute Myelogenous Leukemia | IT | Information Technology |
| ARS | Acute Radiation Syndrome (also known as Acute Radiation Sickness) | IRB | Institutional Review Board |
| ASBMT | American Society for Blood and Marrow Transplantation | JCAHO | Joint Commission on Accreditation of Healthcare Organizations |
| ASHI | American Society for Histocompatibility and Immunogenetics | KIR | Killer Immunoglobulin-like Receptor |
| B-LCLs | B-Lymphoblastoid Cell Lines | NCI | National Cancer Institute |
| BARDA | Biomedical Advanced Research and Development Authority | MHC | Major Histocompatibility Complex |
| BMT CTN | Blood and Marrow Transplant - Clinical Trials Network | MICA | MHC Class I-Like Molecule, Chain A |
| BRT | Basic Radiation Training | MICB | MHC Class I-Like Molecule, Chain B |
| C&A | Certification and Accreditation | MDACC | MD Anderson Cancer Center |
| CBMTG | Canadian Blood and Marrow Transplant Group | MSKCC | Memorial Sloan-Kettering Cancer Center |
| CBB | Cord Blood Bank | MUD | Matched Unrelated Donor |
| CBC | Congressional Black Caucus | NEMO | |
| CBS | Canadian Blood Service | NCBM | National Conference of Black Mayors |
| CBU | Cord Blood Unit | NHLBI | National Heart Lung and Blood Institute |
| CHTC | Certified Hematopoeitic Transplant Coordinator | NIH | National Institutes of Health |
| CIBMTR | Center for International Blood & Marrow Transplant Research | NIMS | National Incident Management System |
| CLIA | Clinical Laboratory Improvement Amendment | NK | Natural Killer |
| CME | Continuing Medical Education | NMDP | National Marrow Donor Program |
| CMF | Community Matching Funds | NRP | National Response Plan |
| COG | Children's Oncology Group | NST | Non-myeloablative Allogeneic Stem Cell Transplantation |

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|---|---|---|---|
| CREG | Cross Reactive Groups | OCR/ICR | Optical Character Recognition/Intelligent Character Recognition |
| CSS | Center Support Services | OIT | Office of Information Technology |
| CT | Confirmatory Testing | OMB | Office of Management and Budget |
| CTA | Clinical Trial Application | ONR | Office of Naval Research |
| DC | Donor Center | P2P | Peer-to-Peer |
| DIY | Do it yourself | PBMC | Peripheral Blood Mononuclear Cells |
| DKMS | Deutsche Knochenmarkspenderdatei | PBSC | Peripheral Blood Stem Cell |
| DMSO | Dimethylsulphoxide | PCR | Polymerase Chain Reaction |
| DNA | Deoxyribonucleic Acid | PSA | Public Service Announcement |
| D/R | Donor/Recipient | QC | Quality control |
| EBMT | European Group for Blood and Marrow Transplantation | RCC | Renal Cell Carcinoma |
| EM | Expectation Maximization | RCI BMT | Resource for Clinical Investigations in Blood and Marrow Transplantation |
| EMDIS | European Marrow Donor Information System | REAC/TS | Radiation Emergency Assistance Center/Training Site |
| ERSI | Environment Remote Sensing Institute | RFP | Request for Proposal |
| FBI | Federal Bureau of Investigation | RFQ | Request for Quotation |
| FDA | Food and Drug Administration | RG | Recruitment Group |
| FDR | Fund Drive Request | RITN | Radiation Injury Treatment Network |
| Fst | Fixation Index | SBT | Sequence Based Typing |
| GETS | Government Emergency Telecommunications Service | SCTOD | Stem Cell Therapeutics Outcome Database |
| GCSF | Granulocyte-Colony Stimulating Factor (also known as filgrastim) | SG | Sample Group |
| GIS | Geographic Information System | SLW | STAR Link® Web |
| GvHD | Graft vs Host Disease | SSA | Search Strategy Advice |
| HCT | Hematopoietic Cell Transplantation | SSO | Sequence Specific Oligonucleotides |
| HHS | Health and Human Services | SSP | Sequence Specific Primers |
| HIPAA | Health Insurance Portability and Accountability Act | SSOP | Sequence Specific Oligonucleotide Probes |

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|---|---|---|---|
| HLA | Human Leukocyte Antigen | STAR® | Search, Tracking and Registry |
| HML | Histoimmunogenetics Mark-up Language | TC | Transplant Center |
| HR | High Resolution | TED | Transplant Essential Data |
| HRSA | Health Resources and Services Administration | TNC | Total Nucleated Cell |
| HSC | Hematopoietic Stem Cell | TSA | Transportation Security Agency |
| IBWC | Immunobiology Working Committee | UI | User Interface |
| IDM | Infectious Disease Markers | URD | Unrelated Donor |
| IHWG | International Histocompatibility Working Group | WGA | Whole Genome Amplification |
| IPR | Immunobiology Project Results | WMDA | World Marrow Donor Association |
| IND | Investigational New Drug | WU | Work-up |